Remarks

Introduction

Status of claims

Claims 1-3 and 5-19 are pending.

All claims have been amended to reflect that the three dimensional structure of the food additives according to the invention is of importance. This three dimensional structure is disclosed throughout the specification and, thus, no new matter has been added.

The Office Action

Claims 1-3 and 5-19 have been examined on the merits.

Rejection under 35 USC § 103

Claims 1-3 and 5-10 have been rejected under 35 U.S.C § 103(a) as being unpatentable over Ueda et al. (US 5,429,832) for the reasons of record and for the additional reason that it is known to coat with chitosan which is a polysaccharide and which is known to be a shell former.

Claims 1, 2, 6 and 8- 10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Ghani for the reasons of record.

Claims 11-19 have been rejected as being unpatentable over Ghani as applied to claims 1,2 and 8-

10 and in further view of Ardaillo et al. and Hessel et al..

Summary of the Examiner's position

It is the Examiner's position that Applicant's argument concerning the distinction between the microgranules of Ghani and the microcapsules of the present invention is not persuasive because a method of making a composition is not given any weight in a claim to the composition.

It is the Examiner's further position that arguing that the method of making the composition affects whether the fibres are surrounded on all sides by coating does not mean that the coating is complete. It is further believed that the picture supplied with Applicant's last response does not support Applicant's arguments, as the coating allegedly shows a crack. On the other hand it is not seen that the Ghani particles are perforated and that even if they were, Applicant's claims would not state any degree of encapsulation. The method of making the product is not given any patentable weight.

Concerning the Ueda et al. reference it is the Examiner's position that fats are not mandatory in Ueda et al. and that emulsifiers can be present as in Applicant's claim 1 in the shell-forming part. Concerning Applicant's argument that Ueda et al. do not disclose complete surrounding with chitosan, it is the Examiner's position that the reference discloses as much as is claimed in the present application, specifically as not limitations are given as to the degree of encapsulation, thickness etc..

Response to arguments

Applicant would like to clarify an inconsistency in the Office Action. On page 2 of the Action claims 11-19 have been rejected over Ghani in further view of Ardaillon et al. and Hessel et al.. On page 3 of the Action references Hessel and Behr et al. are discussed. Clarification is requested. For the purpose of this response it is assumed that the rejection over Ardaillon et al. and Hessel et al. was meant to be a rejection over Behr et al. and Hessel et al.

Concerning the method of making the compositions and the difference between microgranules and microcapsules, Applicant wishes to emphasize that it does make a difference whether the compositions are in the form of a microgranule or a microcapsule. Attached hereto is a Declaration under 37 C.F.R. §1.132 of Professor Benno Kunz, who is also one of the inventors. In paragraph 15 of his Declaration Prof. Kunz explains the fundamental differences between a granule and a capsule. He states that due to the homogeneous distribution of components in a (micro)granule the physical properties can be fundamentally different from the properties of a heterogeneously distributed (micro)capsule. In fact this is proven in the comparison between Applicants microcapsules and Ghanis microgranules (c.f. Declaration at paragraphs 13 and 14). Ghanis microgranules rapidly disintegrate in aqueous invironment, whereas Applicant's microcapsules withstand hydrolytical degradation all the way until to the intestinal tract (c.f. specification at paragraph bridging pages 13/14). It is only here that the shell disintegrates and releases its content (e.g. the bioactive substance). Thus, even if there were identity or overlap to a large extend in the chemical compositions of Ghani's microgranules and Applicant's microcapsules, the difference in three-dimensional arrangement of the individual components leads to at least one totally different physical property (hydrolysis). Therefore, Applicants microcapsules are unobvious over Ghanis microgranules.

To emphasize the importance of the three-dimensional structure Applicant has amended the claims from a (chemical) composition to a spherical device.

Concerning the Examiner's statement of possible incomplete coating Applicant wishes to point out that the core material in Applicant's invention is not coated but rather encapsulated. With encapsulation, other than with coating. there is no "degree" of encapsulation. Either the core material is free or it is encapsulated. Capsules show a distinct phase boundary between the interior and exterior of the capsule. This is evident from the picture attached to the last response and which picture is resubmitted as an Attachment to Professor Kunz's Declaration together with this

amendment. The picture clearly shows the (spherical) phase boundary between the inside of the sphere and the outside of the sphere. Professor Kunz states in paragraph 12 of his Declaration that what is recognized by the Examiner as a "break" in the coating actually is a pleat in the shell. This pleat has no influence whatsoever on the integrity of the capsule.

Finally, concerning reference Ueda et al. it is indeed Applicant's position that fatty acids or fats or oils are mandatory in Ueda et al.'s coating composition. The Examiner is correct when she states that col. 4, lns. 59-70 discloses fats and chitosan as part of a Markush grouping and emulsifiers as part of a second Markush grouping. Therefore, a combination of elements of the two groups would not necessarily have to contain fats, fatty acids or oils. However, the Examiner has overlooked the paragraph immediately following col. 4, lns. 59-70, which reads:

> *At least one substance selected from the group consisting of linear or branched saturated fatty acids having from 14 to 22 carbon atoms, hardened animal oils and fats, hardened vegetable oils and fats and waxes is incorporated into the coating composition....*

Thus, it is clear that the coating composition does contain at least a fatty acid, a fat or an oil, and Applicant's arguments presented in the last response are valid and are not repeated here.

As for the rejection of claims 11-19 over Ghani in view of Ardaillion et al an Hessel et al. which is taken to be a rejection over Ghani in view of Hessel et al. and Behr et al. it is Applicants position that such a combination does not yield in Applicant's invention. As already pointed out above Ghani discloses a granule and not a capsule. Therefore, any combination with Ghani can also only result in a granule. Additionally, the present application relies on a priority of 22 December 1999, which is prior to the publication date of Hessel et al.. It is therefore not a reference which can be applied against the present application.

The Behr et al. reference suffers from the same disadvantage as the Ueda reference. Behr et al. use

an oil, fat, wax or fatty acid in the coating composition (c.f. Behr et al at col. 13, lns. 5-23 and all encapsulation experiments). Moreover, there is no mentioning of the inclusion of a biologically active component in the core. It is not seen in which way Behr et al. can compensate the deficiencies in primary reference Ghani.

In view of the foregoing amendments and comments, Applicant respectfully requests an early Notice of Allowance in the instant application.

Should Examiner Helen F. Pratt have any questions regarding the present application, the Examiner is invited to contact the undersigned.

Respectfully submitted

.....
Klaus Schweitzer
see attached limited recognition

ProPat, L.L.C.
2912 Crosby Road
Charlotte, NC 28211
Phone (704) 365-4881
Fax (704) 365-4851